IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE
8 N. Main Street, Suite 100
Dayton, OH 45402;

OHIO CHAMBER OF COMMERCE
34 S. Third Street, Suite 100
Dayton, OH 45402;

MICHIGAN CHAMBER OF COMMERCE
600 S. Walnut Street
Lansing, MI 48933;

CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA
1615 H Street NW
Washington, DC 20062,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201;

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244;

CENTERS FOR MEDICARE AND MEDICAID SERVICES
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

No. 3:23-cv-00156-TMR-PBS

AMENDED AND SUPPLEMENTAL COMPLAINT

Plaintiffs Dayton Area Chamber of Commerce ("Dayton Area Chamber"), Ohio Chamber of Commerce ("Ohio Chamber"), Michigan Chamber of Commerce ("Michigan Chamber"), and Chamber of Commerce of the United States of America ("U.S. Chamber") bring this action for declaratory and injunctive relief against the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") and the heads of those agencies in their official capacities (collectively, "Defendants"), alleging as follows:

INTRODUCTION

1. This lawsuit is a constitutional challenge to the prescription drug price control program established by the "Inflation Reduction Act of 2022" ("IRA"), 42 U.S.C. § 1320f *et seq*. The IRA uses the term "negotiation" to mislead the public into believing that a voluntary and fair bargaining process will take place between the government and pharmaceutical companies. The reality, however, is that Congress has not set up a negotiation at all. Congress created an unprecedented, one-sided regime that forces manufacturers to sell drugs at government-set prices. The appropriate term for this is "mandated price control," not "negotiation."

2. The IRA's price control program is not only a disastrous error of public policy; it is illegal. The program is a violation of America's fundamental constitutional requirements of limited government, property rights, the rule of law, and the separation of powers.

3. The program represents a dramatic transformation in the market-based pricing rules that have governed Medicare for decades. Manufacturers that signed up to participate in Medicare—and invested billions of dollars in developing and distributing drugs that serve Medicare beneficiaries—never signed up for the IRA.

4. When Congress delegates authority to an administrative agency to impose price controls, the momentous nature of the delegation and the potential consequences for both private

rights and the public as a whole raise fundamental separation-of-powers and other serious constitutional concerns.

5. It is therefore incumbent upon Congress to abide by traditional and constitutionally required guardrails for protecting private rights and avoiding abuses of power by government officials. Congress must provide legal standards to constrain the agency to ensure that the prices imposed are not arbitrary, confiscatory, or unduly discriminatory. Congress must also establish adequate procedures, including meaningful opportunities for public input, to ensure that the agency is well informed and that regulated parties have an opportunity to be heard. And Congress must provide adequate opportunities for judicial review to ensure that the agency operates within the bounds of the law, actually adheres to the applicable constitutional and legal standards, and does so consistently and fairly across cases.

6. These safeguards are essential to preserving accountability, ensuring that the agency is not acting outside the scope of its lawful authority, and protecting the important due process rights that are implicated when the government displaces market forces and sets prices on targeted products through central planning. Such protections are especially important when the government is acting simultaneously as both a regulator and in its own self-interest as the dominant market participant.

7. These safeguards also protect the important public interests at stake, particularly where the scheme involves the nation's healthcare markets. The public has an extremely strong interest in protecting the incentives to drive innovation toward developing new cures and treatments for diseases and serious health conditions. Those incentives depend on a market-based system for financing research and development. Requiring pharmaceutical manufacturers to sell their drugs at unfairly low, government-mandated prices will disrupt and endanger vital research

and development, eliminate jobs, deprive patients of access to life-saving and life-enhancing therapies, increase the overall long-term costs of care, and discourage investment in a sector that is critical for our nation's security as well as the public health.

8. For decades, federal healthcare programs used market-oriented pricing standards that respected manufacturers' property rights and allowed America to become the world leader in pharmaceutical innovation. The IRA throws all of that out the window. It purports to grant HHS authority to accomplish a massive takeover of prescription drug pricing in America, and it gives HHS this radical new authority while eliminating multiple layers of safeguards and protections that the Constitution demands.

9. Rushed through a budget reconciliation process without debate and enacted on a bare party-line vote, the IRA's misleadingly named "Drug Price Negotiation Program" is a novel experiment that dramatically expands bureaucratic control over the private economy. The statute seeks to upend the nation's healthcare markets by granting an administrative agency, for the first time, unfettered discretion to impose arbitrary prices on an expanding roster of dozens of prescription drugs that are among the most important to patient care, while coercing manufacturers into feigning "agreement" with the agency's chosen prices.

10. The name of the program is deliberately misleading, as the IRA does not provide for anything that could conceivably be called a "negotiation." Instead, it authorizes the Secretary of HHS to pick a price as low as he or she chooses and compels manufacturers to "agree" that whatever price the Secretary dictates is the "maximum fair price." In a true negotiation, if the parties cannot reach mutually agreeable terms and pricing, they can walk away. But that is not possible under this statute.

11. The IRA's grant of authority to HHS is all the more breathtaking because the IRA lacks the traditional, constitutionally required safeguards that constrain administrative price-setting schemes. Instead, the IRA is custom-built to eliminate political and legal accountability for HHS decision-making and to maximize the agency's unfettered and unchecked power.

12. If all that Congress wanted to accomplish was to limit the price paid by the government for prescription drugs in federal healthcare programs, the IRA's unprecedented approach would be wholly unnecessary.

13. But openly legislating price controls on critical prescription drugs would be politically untenable. And creating a genuine "negotiation" process could lead to prices that are reasonable and market-based, rather than confiscatory or arbitrary. Congress wanted price controls without incurring a political cost for imposing them. So Congress crafted the IRA's sham "negotiation" scheme to hide that reality, empowering HHS to transform the nation's drug markets without taking political responsibility for the inevitable upheaval or facing judicial scrutiny.

14. If one party can fix the outcome and the other party has no choice but to accept it, that is not a negotiation. An "agreement" to accept whatever the other party decrees is not an agreement to "negotiate"—it is an acknowledgment that the other party has the power to make you an "offer" you can't refuse.

15. The IRA purports to give HHS just such a power: it requires manufacturers to "agree[ ]" to enter its "negotiation" process knowing that they will have no choice but to accept whatever price HHS unilaterally dictates at the end of that process. *See* 42 U.S.C. § 1320f-2; *id.* § 1320f-4.

16. The IRA's euphemistic references to the manufacturer's "agreement" and the parties' "negotiations" are matched by the IRA's imposition of a misleadingly named "excise tax"

to force manufacturers to "agree" to whatever the Secretary dictates. The IRA is ostensibly intended to reduce prescription drug prices. But if a manufacturer refuses to "agree" to whatever HHS decides is the "maximum fair price," the manufacturer is hit with an "excise tax" penalty of up to *19 times* the daily gross sales of the drug—*all* U.S. sales, not just sales in connection with government healthcare programs. This is no tax; it is more like an *ax.* Because no one could afford to pay such an exorbitant penalty, the purported "tax" is in reality an ultimatum to pharmaceutical companies: "agree" to whatever price the government names, or we'll smash up your business. Congress itself proved the true nature of the "excise tax" by projecting that it will raise precisely *zero* revenue.

17. In short, the IRA's purported "negotiation" regime is Orwellian through and through: it is designed to maximize government power while evading public accountability. If Congress is allowed to do this to the pharmaceutical industry, who will be next?

18. Congress could have set a legal standard for HHS to apply in fixing the price, but then Congress would have had to be open about the fact that that is what is happening in this new regime. Rather than own up to that, Congress delegated vast, unchecked power to the Secretary to set a price as low as he or she wishes, with no legal standard (or any other intelligible principle) constraining the Secretary's discretion.

19. Congress could have provided for judicial and administrative review to ensure that the prices set by HHS are reasonable and fair and that HHS avoids arbitrary or otherwise unlawful results in setting prices, but then judicial review would expose the reality of what HHS was doing and would make it harder for HHS to impose confiscatory or arbitrary prices. So instead Congress sought to bar judicial review of many important decisions to be made by HHS, including decisions about the drugs to include in this price control regime and about the prices to impose. Blanketing

the statute with multiple bars of judicial review is particularly reflective of the games Congress is trying to play with the Constitution.

20. Congress could have imposed price controls without forcing manufacturers to pretend that they "agree" that the price set by HHS is the "maximum fair price," but, again, then Congress would have had to own up to the fact that it was imposing price controls. So instead Congress built compelled speech into its falsely labeled "negotiation" regime.

21. There is no way for manufacturers to avoid the sham "negotiation" process or the agency-imposed price controls. If a manufacturer has one drug selected by HHS for "negotiation," it has no legal avenue to remove the drug from Medicare and Medicaid and thereby avoid the price control regime. Instead, the manufacturer would have to remove *all* its drugs from Medicare and Medicaid. That would create a public health disaster for millions of Medicare and Medicaid beneficiaries. Such a total withdrawal from government healthcare programs would also be economically infeasible; given the government's domination of the nation's healthcare markets, that all-or-nothing choice is no choice at all.

22. Moreover, even if a manufacturer somehow found it economically feasible to leave all government healthcare programs, withdrawing is a long and uncertain process as a legal matter. In particular, while HHS has attempted to mask this reality via non-binding guidance, immediate withdrawal from Medicare Part D is not permitted by the underlying Medicare statute. At best, statutorily required delays mean that it would take 11 to 23 months for a manufacturer to extract itself from Medicare Part D—and the manufacturer would be subject to the IRA's punitive "excise tax" in the meantime. As a result, manufacturers have neither a legal nor a practical ability to escape the IRA's price control scheme.

23. Meanwhile, the price control scheme will have far-reaching consequences well beyond the confines of federal healthcare programs. Because manufacturers will face crippling penalties unless they publicly "agree" that the artificially low agency-imposed price is the "maximum fair price," they will be prejudiced in their ability to negotiate different prices in private markets. And HHS's price controls will dramatically reduce manufacturers' ability to invest in research and development to bring new drugs to patients—to the detriment of all Americans and future generations. Some have sought to downplay the IRA's effect on innovation, but it is no accident that the United States has the highest level of pharmaceutical innovation and that countries where governments are more involved in setting prices have less innovation.

24. This unprecedented regime of price controls and forced sales flouts bedrock principles of separation of powers and nondelegation, exceeds Congress's enumerated powers, denies pharmaceutical manufacturers due process of law, imposes excessive fines, and compels speech in violation of the First Amendment.

25. For these reasons, and as further explained below, this Court should declare the IRA's drug pricing scheme unconstitutional and enjoin its enforcement.

JURISDICTION AND VENUE

26. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 703–06.

27. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States, at least one Plaintiff resides in this district, and no real property is involved in this action.

THE PARTIES

28. Plaintiff Dayton Area Chamber of Commerce brings together more than 2,200 businesses and organizations in a 14-county area surrounding Dayton, Ohio. The Dayton Area Chamber strives to improve the region's business climate and overall standard of living through public policy advocacy, economic development initiatives, and providing networking and training opportunities for its members. The Dayton Area Chamber is widely recognized for its innovative programs and outstanding contribution to positive change in the region.

29. Plaintiff Ohio Chamber of Commerce, founded in 1893, has long been an advocate and a resource for businesses throughout the Buckeye State. The Ohio Chamber has nearly 8,000 members, including individually owned and operated businesses serving small communities as well as publicly traded corporations operating on a global scale. The Ohio Chamber through its ten policy committees develops public policy positions on both state and federal matters for the benefit of its members. The Ohio Chamber is an Ohio organization organized as a 501(c)(6) trade organization.

30. Plaintiff Michigan Chamber of Commerce is Michigan's leading state-wide business advocacy organization, representing approximately 4,000 members who employ more than 1 million people. Its membership includes businesses big and small, trade associations, and local chambers of commerce representing all 83 Michigan counties and a variety of industries. For over 60 years, the Michigan Chamber has been a champion for good public policy. Using its voice to advance member priorities through legislative, legal, and political action, the Michigan Chamber's goal is to achieve policies that benefit members, their employees, and in turn the people of the State of Michigan by enhancing the quality of life for Michigan families.

31. Plaintiff Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 members, including members in

this District, and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. Among other things, the U.S. Chamber works with federal and state governments to improve our nation's healthcare system by achieving meaningful transparency, promoting consumer choice, and supporting reforms that yield greater value to patients and employers. The U.S. Chamber is a 501(c)(6) nonprofit organization headquartered in Washington, D.C.

32. Defendant Xavier Becerra is the Secretary of the Department of Health and Human Services ("the Secretary"). He oversees the Medicare program, among other things, and is responsible for administering the statutory provisions challenged here. He is sued in his official capacity only.

33. Defendant HHS is an executive department of the United States government headquartered in Washington, D.C. HHS is responsible for administering the Medicare program and the statutory provisions challenged here.

34. Defendant the Centers for Medicare and Medicaid Services ("CMS") is an administrative agency within HHS that is headquartered in Baltimore, MD, and that administers the Medicare program and the statutory provisions challenged here.

35. Defendant Chiquita Brooks-LaSure is the CMS Administrator. She administers the Medicare program and the statutory provisions challenged here on behalf of the Secretary. She is sued in her official capacity only.

STANDING

36. Plaintiffs have associational standing because each of them has members that are directly subject to the IRA's price controls and adversely affected by them and thus would have standing to sue in their own right; because the interests Plaintiffs seek to protect are germane to their policy aims; and because neither the claims asserted nor the relief requested requires an

individual member to participate in this suit. The IRA is depriving Plaintiffs' members of their constitutional rights, making it more difficult for them to operate their businesses, and stifling healthcare innovations that all of us depend on. The IRA is also harming Plaintiffs' members by requiring the disclosure of competitively sensitive proprietary information, including trade secrets.

37. For example, the pharmaceutical company AbbVie Inc. ("AbbVie"), which is a member of all four Plaintiffs, manufactures the drug IMBRUVICA®, which was one of the ten drugs that the Secretary selected for IRA price-setting on August 29, 2023. AbbVie is engaged in producing, preparing, packaging, labeling, and distributing IMBRUVICA®. There are three different formulations of IMBRUVICA®: oral suspension, capsules, and tablets. AbbVie performs activities of a "manufacturer" for all three of these formulations.

38. For instance, for the tablet formulation of IMBRUVICA®, AbbVie receives bulk powdered active ingredient at an AbbVie manufacturing facility and produces tablets. AbbVie then adds various coatings and colorings to the tablets, and packages them in blister-packs and bottles. AbbVie labels those packages with the FDA-required product labeling and delivers them to distributors.

39. AbbVie is therefore a "manufacturer" of IMBRUVICA® in the ordinary sense of the term and under the IRA's statutory definition, which defines a "manufacturer" subject to the price control program, in relevant part, as "any entity which is engaged in—(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products . . . or (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." 42 U.S.C. § 1396r-8(k)(5); *see id.* § 1320f (cross-referencing § 1395w-3a(c)(6)(A), which in turn references § 1396r-8(k)(5)).

40. IMBRUVICA® was originally developed by Pharmacyclics, Inc., now known as Pharmacyclics LLC ("Pharmacyclics"). AbbVie acquired Pharmacyclics as a wholly owned subsidiary on May 26, 2015 for approximately $21 billion.

41. Pharmacyclics remains the holder of the FDA-approved New Drug Applications ("NDAs") for IMBRUVICA®.

42. Pharmacyclics is also a member of all four Plaintiffs.

43. Even though AbbVie is a manufacturer of IMBRUVICA® within the meaning of the IRA and will bear many of the burdens and costs of the IRA "negotiation" regime, CMS has indicated in non-binding guidance that it considers the NDA holder for the selected drug to be the "primary manufacturer" (a term that does not appear in the IRA). *See* Memorandum from CMS on Revised Guidance for Medicare Drug Price Negotiation Program ("Revised Guidance"), at 118 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

44. Pharmacyclics is not a publicly traded company and does not independently report its financial performance. Rather, AbbVie reports IMBRUVICA® sales in its own consolidated financial statements. *See, e.g.*, AbbVie Inc., Annual Report (Form 10-K) (Feb. 17, 2023), https://investors.abbvie.com/node/17526/html.

45. When IMBRUVICA®'s financial performance is impaired (as will occur unless the IRA's price-setting process is enjoined), AbbVie suffers injury. For example, a July 29, 2022 article by Bloomberg entitled "AbbVie Slides After Cutting Sales Outlook on Cancer Drug Decline" reported that "AbbVie Inc. shares slide more than 6% Friday after the company cut its full-year sales outlook on weak performance from cancer drug Imbruvica." Angelica Peebles,

https://www.bloomberg.com/news/articles/2022-07-29/abbvie-slides-after-cutting-sales-outlook-on-cancer-drug-decline#xj4y7vzkg.

46. According to CMS data, IMBRUVICA® was among the drugs with the top ten gross annual Part D expenditures for plan year 2021. *See* CMS, *Medicare Part D Spending by Drug* (Mar. 6, 2023), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug. Based on that data, market analysts correctly predicted that IMBRUVICA® would be among the ten drugs selected by the Secretary for the IRA's price controls by September 1, 2023.

47. Given the substantial risk that IMBRUVICA® would be selected and the statutory timeline, AbbVie and Pharmacyclics had no reasonable choice but to begin incurring the significant costs associated with complying with the IRA before the Secretary confirmed that IMBRUVICA® was selected, including but not limited to the collection and synthesis of massive quantities of complex, commercially sensitive information for submission to CMS by October 2, 2023. Under the IRA, manufacturers that failed to submit that information by the deadline would face penalties of $1 million per day. *See* 42 U.S.C. §§ 1320f-6(c), 1320f-2(a). Manufacturers that failed to submit that information by the deadline would also face imposition of the IRA's "excise tax." 26 U.S.C. § 5000D(b)(4).

48. Both AbbVie and Pharmacyclics have borne, and will continue to bear, significant costs and burdens associated with the selection of IMBRUVICA® for the IRA's price-setting process. More than 30 AbbVie employees were engaged in identifying, collecting, reviewing, and preparing to submit the data required under the IRA by October 2, 2023. AbbVie needed to hire outside consulting firms to advise on and assist with the collection and review of the data. AbbVie has also had to create an entirely new, full-time internal department to support activities related to

the IRA price-setting process, taking employees away from previous responsibilities unrelated to the IRA. Approximately 15 Pharmacyclics employes were also engaged in identifying, collecting, reviewing, and preparing to submit the required data by October 2, 2023.

49. To avoid the IRA's crippling "excise tax" on sales of IMBRUVICA®, Pharmacyclics was forced to sign an "agreement" to "negotiate" with CMS on September 29, 2023. The agreement was executed by an AbbVie employee acting on behalf of Pharmacyclics.

50. The so-called "agreement" to "negotiate" functions as a blank check to the government to saddle manufacturers with whatever burdens it wants. The CMS agreement gives the government unilateral power to change the terms of the "agreement" at any time for any reason. *See* CMS, Medicare Drug Price Negotiation Program Agreement, at 4, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf ("CMS Template 'Agreement'"). It expressly disclaims the government's responsibility for any costs incurred by manufacturers in connection with the agreement. *Id*. And it commits manufacturers to agree to whatever the government, in its statutorily unreviewable discretion, ultimately deems the "maximum fair price." *Id.* at 2.

51. Now that IMBRUVICA® has been selected and is subject to an "agreement" to "negotiate" with CMS, personnel employed by AbbVie and Pharmacyclics will conduct the burdensome "negotiation" process for IMBRUVICA®.

52. The "negotiation" process has imposed and will continue to impose substantial costs on AbbVie and Pharmacyclics, including the expenditure of employee time and financial resources to collect and submit data required at the outset of the "negotiation" process, collect and prepare data in response to follow-up requests for data from CMS throughout the "negotiation" process, collect and prepare to submit data on drugs that could be selected in subsequent years,

perform "corrective action" if CMS determines at any time that any portion of the data submission was incomplete or inaccurate, evaluate CMS's "offer," formulate a "counteroffer" that meets CMS's detailed specifications (*see* Revised Guidance at 155–56), and communicate with CMS throughout the statutory "negotiation period." AbbVie and Pharmacyclics will also need to spend time and money to determine how to operationalize the provisions of the IRA that require manufacturers to provide access to the "maximum fair price" for "maximum fair price eligible individuals." *See* 42 U.S.C. §§ 1320f-2, 1320f-6.

53. Both AbbVie employees and Pharmacyclics employees have needed to participate, and will continue to need to participate, in gathering and submitting information to CMS for purposes of the IRA price-setting process, responding to CMS's requests for information, and responding to CMS's "offer" because AbbVie and Pharmacyclics have access to different components of the relevant information.

54. It is well-established that "compliance costs are a recognized harm for purposes of Article III" standing. *Kentucky v. Yellen*, 54 F.4th 325, 342–43 (6th Cir. 2022) (finding Article III injury where plaintiff needed to spend "time and money" to ensure compliance with provision of American Rescue Plan Act of 2021); *see also Czyzewski v. Jevic Holding Corp*., 580 U.S. 451, 464 (2017) ("For standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'"); *Nat'l Rifle Ass'n v. Magaw*, 132 F.3d 272, 280–82 (6th Cir. 1997) (finding Article III injury where gun manufacturers suffered economic harm "in order to comply" with new federal gun law).

55. As the Sixth Circuit has observed, the Supreme Court has also "found standing based on a substantial risk that [a] harm will occur, which may prompt plaintiffs to reasonably incur costs to mitigate or avoid that harm, even where it is not literally certain the harms they identify will come about." *Galaria v. Nationwide Mut. Ins. Co*., 663 F. App'x 384, 388–89 (6th

Cir. 2016) (quotation marks omitted); *see also, e.g.*, *Ohio Coal Ass'n v. Perez*, 192 F. Supp. 3d 882, 902–03 (S.D. Ohio 2016) (finding that "compliance burdens" constituted an "injury in fact" where companies incurred costs to "prepare corrective action plans" in light of "substantial risk" of enforcement of new regulation carrying significant penalties).

56. The IRA contains no price floor for selected drugs and directs CMS to pick the "lowest" price below a statutory ceiling ranging from 25% to 60% lower than a market-based benchmark. *See* 42 U.S.C. § 1320f-3(c)(1)(C), (b)(1), (b)(2)(f).

57. There is at least a "substantial risk," and in fact a very high likelihood, that absent an injunction AbbVie and Pharmacyclics will be forced to "agree" to the Secretary's unreasonably low "maximum fair price," which will be substantially lower than current market prices for IMBRUVICA®. Both AbbVie and Pharmacyclics will be bound by that "maximum fair price."

58. A recent study found that, even in the (highly unlikely) best-case scenario for AbbVie and Pharmacyclics, in which CMS sets the price of IMBRUVICA® at the IRA's statutory ceiling, IMBRUVICA® would sell at a dramatic discount to recently prevailing prices. *See* Inmaculada Hernandez et al., *Estimated Discounts Generated by Medicare Drug Negotiation in 2026*, 29 J. Managed Care Specialty Pharm. 868 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10397328/.

59. Many of Plaintiffs' members are being and will be similarly harmed by the IRA's price control program, which disrupts the entire pharmaceutical development ecosystem.

60. The individual participation of Plaintiffs' members is unnecessary because Plaintiffs seek only "prospective or injunctive relief for [their] members." *Sandusky Cnty. Democratic Party v. Blackwell*, 387 F.3d 565, 574 (6th Cir. 2004) (per curiam) (quoting *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996)). Because

Plaintiffs' suit raises pure questions of law, not a request for damages, individualized proof is unnecessary and the individual participation of Plaintiffs' members is not required.

BACKGROUND

I. The Federal Healthcare and Prescription Drug Markets

61. Over the past several decades, as Medicare, Medicaid, and other federal healthcare programs have expanded, they have displaced private payors and accumulated an ever-increasing share of national healthcare spending. The federal government accounts for nearly half of the nation's total healthcare expenditures.[1] Medicare by itself comprises more than a fifth of the nation's healthcare spending and approximately a third of national spending on prescription drugs.[2] For IMBRUVICA®, Medicare and Medicaid together account for more than 60% of all U.S. sales.

62. In the healthcare field, the federal government acts as both a regulator and the dominant market participant. HHS wields extensive authority under an array of federal statutes and regulations, and the government is by far the largest purchaser and payor of healthcare products and services, including pharmaceuticals. This dual role raises the obvious danger that the government will use self-serving rules to tilt the playing field in its favor and disadvantage other market participants or counterparties.

63. As a practical matter, it is impossible for most pharmaceutical manufacturers not to participate in the federal healthcare markets. That is both because of the size of those markets and because they are not true markets. When drug manufacturers participate in Medicaid, for example,

[1] Ricardo Alonso-Zaldivar, *Government headed for close to half of nation's health tab*, AP News (Feb. 20, 2019), https://apnews.com/article/health-north-america-local-governments-baby-boomers-health-care-costs-5dc460ae8d8b4c8a93c6c3108fd71e9c.

[2] Juliette Cubanski & Tricia Neuman, *What to Know about Medicare Spending and Financing*, KFF (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/#:~:text=Medicare%20plays%20a%20major%20role,drug%20sales%20(Figure%201).

they are not at liberty to pick and choose what products to sell; they are either all in or all out. *See* 83 Fed. Reg. 12,770, 12,771, 12,782–83 (Mar. 23, 2018).

64. Medicare and Medicaid, which together comprise nearly 40% of the health insurance market,[3] have long provided reimbursement for drugs using formulae tied to market prices, while still offering significant discounts to low-income and elderly patients.

65. Medicare Part B covers a range of outpatient healthcare services for beneficiaries, including physician-administered drugs. *See* 42 U.S.C. § 1395k(a)(1); *id*. § 1395x(s)(2)(A). Since 2005, Medicare Part B has based payments on market transactions by requiring Medicare to reimburse providers 106% of a drug's Average Sales Price (ASP), which is the average price to commercial purchasers in the United States, inclusive of rebates and other discounts. When ASP data was not available, Medicare Part B paid 103% of the wholesale acquisition cost (WAC) for a drug.

66. Medicare Part D, which Congress created in 2003, covers self-administered prescription drugs. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Congress set up a system whereby HHS would contract with private insurance plans to provide a prescription drug benefit, and Congress gave private companies acting under contract with HHS authority to negotiate drug prices with pharmaceutical companies. In the "noninterference clause" of the provisions of the Medicare statute that established the Part D program, Congress prohibited HHS from setting drug prices or interfering in the market-based negotiations between the plan sponsors and the pharmaceutical manufacturers: the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies

[3] Katherine Keisler-Starkey & Lisa N. Bunch, U.S. Census Bureau, No. P60-278, Health Insurance Coverage in the United States: 2021, at 2 (Sept. 2022), https://www.census.gov/content/dam/Census/library/publications/2022/demo/p60-278.pdf.

and PDP [prescription drug plan] sponsors," and "may not require a particular formulary" or "institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i).

67. That longstanding prohibition made good sense, especially in light of the particular characteristics of the pharmaceutical market.

68. Pharmaceutical companies invest billions of dollars in research and development to discover new drugs, conduct rigorous pre-clinical and clinical testing, and shepherd drugs through the lengthy FDA approval process, with no certainty that a drug will ever make it to the pharmacy shelves. The average cost of bringing a single new drug to market is commonly estimated to be more than $2 billion,[4] and the process takes an average of 10 to 15 years.[5]

69. Only about *1 in 5000* potential new drugs successfully navigates these hurdles; the vast majority are never approved for patient use.[6] And of the minuscule fraction of treatments that are approved, only one-third manage to cover their cost of development.[7]

70. Recognizing the enormous risk-taking and up-front costs entailed by the drug development and approval process, Congress traditionally used market-based pricing mechanisms and afforded drugs certain periods of marketing exclusivity before generic competitors could enter the market.

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[4] Stephen Ezell, Info. Tech. & Innovation Found., *Ensuring U.S. Biopharmaceutical Competitiveness*, at 30 (July 2020), https://www2.itif.org/2020-biopharma-competitiveness.pdf.

[5] GAO, No. GAO-20-2155P, Artificial Intelligence in Health Care, at 34 (Dec. 20, 2019), https://www.gao.gov/assets/gao-20-215sp.pdf.

[6] Paul Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538 (2021), https://doi.org/10.1016/j.csbj.2021.08.011.

[7] John A. Vernon & Joseph H. Golec, AEI, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence*, at 7 (2008), https://www.aei.org/wp-content/uploads/2014/07/-pharmaceutical-price-regulation-public-perceptions_113401853979.pdf.

71. This framework, based on property rights, stable rules, and market-oriented pricing mechanisms, allowed the United States to become the world leader in pharmaceutical innovation, while bringing down the cost of drugs in the long run through competition. From 2004 to 2018, U.S.-headquartered firms produced almost twice as many new drugs as did firms in Europe and three to four times as many new drugs as did firms in Japan.[8] It is no accident that, when the COVID-19 pandemic hit and the world desperately needed treatments and high-quality vaccines, American pharmaceutical companies led the way.

II. The Inflation Reduction Act

A. The IRA's Unprecedented Provisions

72. On August 7 and August 12, 2022, by narrow votes along party lines (51 to 50 in the Senate and 220 to 207 in the House of Representatives), Congress passed an unprecedented bill now known as the Inflation Reduction Act ("IRA").

73. By passing the IRA's drug price control provisions, Congress sought to dramatically reshape the pharmaceutical industry by creating an entirely new rate-setting regime requiring manufacturers to provide their drugs at government-set prices, without providing for any of the accountability, transparency, or oversight controls that the Constitution requires and that Congress has built into other price control statutes.

74. Revising the Medicare Part D "non-interference clause," the IRA now requires HHS to establish what the statute misleadingly calls a "Drug Price Negotiation Program," 42 U.S.C. § 1320f(a), for setting Medicare prices for certain drugs.

[8] Ezell, Ensuring U.S. Biopharmaceutical Competitiveness, *supra* note 4, at 1.

i. Drug selection provisions

75. The Secretary of HHS, by way of delegation to CMS, has already begun to implement the IRA's price-control program. *See* CMS, Medicare Drug Price Negotiation Program, Drug Price Negotiation Timeline for 2026, https://go.cms.gov/3XVTfAn. On March 15, 2023, CMS released a 91-page "initial guidance" document addressing various aspects of the drug selection and price-setting process. *See* Memorandum from CMS on Medicare Drug Price Negotiation Program, https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf (hereinafter "Initial Guidance"). On June 30, 2023, CMS issued a 198-page "revised guidance" document responding to certain comments and making certain changes. *See generally* Revised Guidance. On August 29, 2023, CMS published the first list of selected drugs, including IMBRUVICA®.

76. In 2023, the IRA requires the Secretary to rank "negotiation-eligible drugs" (further explained below) based on total expenditures under Medicare over the past year (initially looking only to Part D expenditures and then expanding to both Part B and Part D). *Id.* § 1320f-1(b)(1)(A)–(B). Because total expenditures are a function of volume as well as price, this ranking includes many of the most commonly used drugs in the country, regardless of whether there is any basis for thinking that those drugs are overpriced. That is particularly true given that CMS has decided to calculate total expenditures on a gross basis, not based on amounts "actually paid" after taking account of rebates or other direct or indirect remuneration. *See* Initial Guidance at 5–6 & n.3; Revised Guidance at 18; 88 Fed. Reg. 22,120, 22,259–63 (Apr. 12, 2023). The agency's calculation of total expenditures thus lacks any real connection to actual Medicare expenditures.

77. The IRA defines "negotiation-eligible drugs" to include all "qualifying single-source drug[s]." *Id.* § 1320f-1(d)(1), (e)(1). Per the statute, for drug products, a qualifying single-source drug is one that (1) is marketed under a new drug application pursuant to 21 U.S.C.

§ 355(c); (2) has been approved by FDA for at least seven years; and (3) is not the reference listed drug for a generic drug marketed under an abbreviated new drug application pursuant to 21 U.S.C. § 355(j). 42 U.S.C. § 1320f-1(e)(1)(A). For biological products, a qualifying single-source drug is one that (1) is marketed under a biologics license application pursuant to 42 U.S.C. § 262(a); (2) has been licensed by FDA for at least 11 years; and (3) is not the reference product for any biosimilar product marketed under 42 U.S.C. § 262(k). *Id.* § 1320f-1(e)(1)(B).[9]

78. In its guidance, CMS has taken a maximally broad view of what constitutes a single "drug." It sweeps in different products—that have different dosage forms, strengths, and routes of administration, that were subject to separate clinical trials, that help different patient populations, and that have different treatment indications—merely because they contain the same active moiety (*i.e.*, molecular basis) or active ingredient and are marketed by the same holder of a new drug application or biologics license application. CMS has thus defined as a single "drug" a wide range of different drug products, including drug products that are marketed pursuant to different new drug applications or biologics license applications. *See* Initial Guidance at 8–10; Revised Guidance at 99–100.

79. Under the statute, a drug approved fewer than seven years ago by FDA is not "negotiation-eligible." But CMS's definition sweeps into the price control regime many drug products that are not "negotiation-eligible" by treating such ineligible drugs as if they are identical to or encompassed by different drug products that are eligible.

80. As a result, while the IRA calls for ten drugs to be "selected" for "negotiation" in the first year, CMS's redefinition of "drug" to encompass families of multiple distinct drug

[9] "Biological products" include a wide range of products such as vaccines, gene therapies, and other treatment technologies. *See* 42 U.S.C. § 262(i)(1); 21 C.F.R. § 600.3.

products means that the IRA's price controls apply to a far greater number of drugs. By significantly expanding the scope of the price control regime, CMS will exacerbate its impact on incentives for innovation.

81. Despite the critical importance of this definition and the substantial legal consequences that flow from it, CMS refused to follow notice-and-comment rulemaking procedures and, instead, expressly stated that it "is issuing guidance [on that subject] as final, without a comment solicitation." Initial Guidance at 2; *see* Revised Guidance at 8-11. CMS has also not provided any transparency into its calculations of Medicare expenditures to determine the selected drug list. And the IRA states that it bars judicial review of the agency's drug selection, insulating the price-setting process from scrutiny and greatly heightening the likelihood of error-laden and arbitrary decision-making.

82. The "negotiation-eligible drugs" are some of the most innovative and widely used drug and biological products in the world. Their high utilization reflects that they are needed by large numbers of patients.

83. Once HHS ranks these "negotiation-eligible drugs" by their Medicare expenditures, the IRA directs HHS to subject a certain number of those drugs to the "negotiation" process.

84. After these "negotiation-eligible drugs" are ranked, the top ten Medicare Part D drugs, based on Medicare expenditures, are to be selected in 2023.

85. By September 1, 2023, the Secretary was required to publish the ten Medicare Part D drugs selected for "negotiation," with the first set of "maximum fair prices" for those drugs taking effect on January 1, 2026. 42 U.S.C. § 1320f(d)(1); *see* § 1320f-1(a)(1).

86. By October 1, 2023, manufacturers of selected drugs were required to sign "agreements" to "negotiate." *Id.* § 1320f(d)(2)(A).

87. By October 2, 2023, manufacturers were required to submit extensive data requested by the Secretary. *Id.* § 1320f(d)(5)(A).

88. By February 1, 2024, HHS will send to each manufacturer the government's initial "offer" of what it would establish as the "maximum fair price" for a specific drug. *Id.* § 1320f(d)(5)(B).

89. By March 2, 2024, each manufacturer must either accept HHS's offer or send a "counteroffer." *Id.* § 1320f-3(b)(2)(C)(i). As explained in more detail later, HHS is free to ignore the manufacturer's "counteroffer."

90. By August 1, 2024, HHS must decide the price that it is imposing, thereby ending the "negotiation" process. HHS then publishes the "maximum fair prices" by September 1, 2024, and the prices go into effect on January 1, 2026. *Id.* § 1320f(d)(5)–(6).

91. This process will then repeat itself annually. On February 1, 2025, fifteen additional Part D drugs will be selected for price controls effective in 2027, and on February 1, 2026, fifteen additional Part D and Part B drugs will be selected for 2028. *Id.* § 1320f(b)(3).

92. Twenty additional Part D and Part B drugs will be selected for 2029 and each year thereafter. *Id.* § 1320f-1(a)(1)–(4).

93. The number of drugs subject to "negotiation" compounds over time: Once a drug is selected, it remains selected until HHS determines that a generic or biosimilar version of the drug is approved or licensed and marketed pursuant to that approval or licensure. *Id.* § 1320f-1(c)(1). By 2029, *sixty* different drugs—and untold numbers of distinct drug products, given CMS's sweeping redefinition of "drug"—will be subject to "negotiated" "maximum fair prices."

94. CMS has acknowledged that the timeline provided in the IRA is "tremendously tight." Celine Castronuovo, *Drug Price Negotiations Need 'Nimble' Approach, Official Says*,

Bloomberg Law (Feb. 13, 2023), https://bit.ly/3IALjyB (quoting principal deputy administrator and chief operating officer of CMS). In its initial guidance, CMS used this congressional deadline as an excuse to forgo notice-and-comment rulemaking, and it has dispensed altogether with public comment on its selection of drugs subject to "negotiation." Initial Guidance at 2.

95. In its revised guidance, CMS warned that "manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list for initial price applicability year 2026," including "gather[ing] information for potential submission to CMS by the statutory deadline of October 2, 2023." Revised Guidance at 9. As noted above, AbbVie and Pharmacyclics heeded this admonition and began the necessary work before the Secretary confirmed that IMBRUVICA® was selected on August 29, 2023.

ii. Forced "negotiation" provisions

96. Once a manufacturer's drug is selected, the parties enter into "negotiations." Congress directed HHS "to achieve the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added). And Congress empowered HHS to "achieve" whatever low price HHS chooses to dictate.

97. The IRA cloaks its price control process in the garb of negotiations, directing HHS to make an "offer" and permitting the manufacturer to "counteroffer." *Id.* § 1320f-3(b)(2)(C)–(D). In a genuine negotiation, if HHS did not want to accept the manufacturer's "counteroffer," it could convey a further counteroffer that the manufacturer, in turn, would be free to accept or to reject in favor of a further counteroffer—or to walk away. But that is not how the IRA "negotiation" process works. After HHS receives the manufacturer's "counteroffer," HHS then sets what it calls the "maximum fair price," and that is the end of the "negotiation." HHS is free to wholly disregard the manufacturer's "counteroffer."

98. During "negotiations," the agency can demand extensive and detailed information, including confidential and proprietary information that a manufacturer would not ordinarily disclose publicly or share with another market participant or potential contracting counterparty, all "in a form and manner specified by the Secretary." *Id.* § 1320f-2(a)(4). Manufacturers must turn over proprietary and trade-secret information to HHS, such as research and development costs; market data for the drug; and costs of production and distribution. *Id.* §§ 1320f-2(a)(4)(B), 1320f-3(e)(1). And manufacturers must provide all that information under the threat of $1 million-per-day penalties and the "excise tax" if HHS believes that they have not timely provided all the information that HHS demanded. *Id.* §§ 1320f-2(a)(4)–(5), 1320f-6(b); 26 U.S.C. § 5000D(b)(4).

99. The IRA also provides that manufacturers must "compl[y] with" whatever requirements HHS unilaterally imposes as "necessary for purposes of administering the program and monitoring compliance with the program." *Id.* §§ 1320f-2(a)(5), 1320f-6(c). The statute guarantees no opportunity for manufacturers even to be heard before these information requirements are imposed, and while CMS allowed a short window for public comment on some aspects of its initial guidance regarding these requirements, the agency has made clear that it will not utilize notice-and-comment rulemaking for any aspect of its implementation of the IRA. *See* Initial Guidance at 2.

100. Although the IRA grants the Secretary broad discretion to demand confidential and other information, it imposes no standards to govern how the Secretary is to use that information to set prices.

101. In fact, there are no clear standards governing how HHS is supposed to set prices at all—and, notably, no limit on how low HHS's "offer" or "maximum fair price" can be. The IRA provides for HHS to "consider" the information provided by the manufacturer, including research

and development costs, unit costs, prior federal financial support, data on pending and approved patent applications, market data and revenue and sales volume data, and information about alternative treatments, 42 U.S.C. § 1320f-3(e), but it does not tell HHS *how* it is supposed to consider that information. Instead, this information goes into a black box, and HHS, unconstrained by any legal standard, produces its "offer."

102. As CMS admits in its guidance, "[w]hile the statute requires CMS to provide an initial offer and a justification, it does not specify how CMS should determine an initial offer nor how or to what degree each factor should be considered." Initial Guidance at 47; *see also* Revised Guidance at 144 ("CMS has the discretion to determine how and to what degree each factor should be considered").

103. While the IRA does not set a floor below which HHS may not descend (apart from a narrow, time-limited exception for certain small manufacturers), the IRA does set a *ceiling* for the "negotiations." 42 U.S.C. § 1320f-3.

104. That ceiling is the lowest number yielded by various alternative calculations specified by the IRA. Each alternative results in a price well below the market price. The IRA limits the ceiling for "negotiations" to between 40% and 75% of a drug's Non-Federal Average Manufacturer Price (Non-FAMP). 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F). Non-FAMP is a measurement of the drug's average net sales price to commercial purchasers and includes all price concessions effectuated through wholesalers. 38 U.S.C. § 8126(h)(5). Non-FAMP is already a net price—meaning the net amount a manufacturer realizes after discounts and rebates—and 40% to 75% of that net price is a very low price.

105. In contrast to the unchecked discretion that it gives HHS, the IRA restricts a manufacturer's ability to "counteroffer," permitting a manufacturer to base a "counteroffer" only

on certain specified factors: research and development costs, and the extent to which they have been recouped; current production and distribution costs; prior federal financial support for development; data on pending and approved patent applications; market data and revenue and sales volume data for the drug; and certain evidence regarding alternative treatments. 42 U.S.C. §§ 1320f-3(b)(2)(C)(ii), 1320f-3(e).

106. The statute is silent regarding how HHS is supposed to decide whether to accept a manufacturer's "counteroffer," except that HHS may not accept any counteroffer that exceeds the statutory ceiling. The statute says only that the Secretary must "respond in writing to such counteroffer." *Id.* § 1320f-3(b)(2)(D). CMS's guidance, for its part, says that the agency will meet with the manufacturer during the "negotiation" process. Initial Guidance Section 60.4.2; *see* Revised Guidance at 61–62. But the guidance conspicuously does not suggest that the agency must or will apply any standard in evaluating the manufacturer's "counteroffer," and the statute supplies no such standard. While it may be polite of the agency to meet with the manufacturer, that is an empty gesture given HHS's unfettered authority to set the price at whatever level it wants.

iii. Government-imposed price

107. Once the Secretary chooses a price, the IRA requires the manufacturer to "agree[]" to that price—which the Secretary then publishes as the "maximum fair price"—and to "agree[]" that it will provide the drug at that price to "maximum fair price eligible individuals." *Id.* §§ 1320f-2(a), 1320f-3(a), 1320f(c)(2). These include all eligible individuals enrolled under Medicare Parts B and D (and enrollees in certain Medicare Advantage plans) and hospitals, physicians, pharmacies, mail order services, and other dispensers with respect to maximum fair price eligible individuals. *Id.* § 1320f-2(a)(1)(A)–(B); *see id.* § 1320f(c)(2).

108. The Congressional Budget Office estimates that CMS's price controls will lower net prices—meaning the price the manufacturer actually receives—for selected drugs by roughly

50 percent on average. Cong. Budget Off., No. 58850, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act (Feb. 2023) https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

109. Manufacturers that fail to provide access to the "maximum fair price" are subject to a civil monetary penalty of *ten times* the difference between the price charged and the "maximum fair price," multiplied by the total number of units sold. 42 U.S.C. § 1320f-6(a).

110. Under this novel price control regime, the Secretary is interested party, judge, jury, and executioner. The Secretary aims for the lowest price, which the Secretary determines in his or her unconstrained and unreviewable discretion, and the Secretary "achieves" it by the simple expedient of unilaterally declaring his or her desired price to be the "maximum fair price." The manufacturer has no legal right and no practical ability to say "no deal" if the agency's "maximum fair price" is in reality confiscatory or unfair. Having "agreed" to "negotiate," the manufacturer is then required to "agree" to the outcome of the "negotiations"—which, again, is whatever HHS wants it to be.

iv. Misnamed and inescapable "excise tax" penalty

111. In a genuine negotiation, if the parties cannot reach mutually agreeable terms and pricing, they can walk away. But Congress designed the IRA's price control program so that a manufacturer cannot walk away.

112. The IRA levies an imposition that it calls an "excise tax" on manufacturers that do not (1) timely "agree" to enter into "negotiation," (2) timely submit the information demanded by the Secretary, or (3) timely "agree" to a "maximum fair price" set by the Secretary. 26 U.S.C. § 5000D(b)(1)–(4).

113. If a manufacturer refuses to "agree" to either the "negotiation" process or the "maximum fair price," it must pay a debilitating and rapidly escalating "excise tax" that amounts

to multiples of *all* U.S. sales of "the designated drug" in any market (not just sales in connection with federal healthcare programs). 26 U.S.C. § 5000D(a), (b); IRA § 11003.[10] And because CMS's guidance treats an entire family of distinct drug products as constituting a single "drug" if the products share an active moiety, this exorbitant "tax" will apply to many distinct drug products all deemed by CMS to be "the designated drug."

114. If a manufacturer refuses to enter into the "negotiation" process at the outset, the excise tax is imposed on the "period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a)." *Id*. § 5000D(b)(1). The Secretary published the first list of selected drugs on August 29, 2023, and starting on October 2, 2023, any manufacturer that refuses to participate in "negotiations" would be required to pay the exorbitant "excise tax."

115. If a manufacturer refuses to "agree" to the "maximum fair price" set by HHS, the "excise tax" applies beginning "on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph)." *Id*. § 5000D(b)(2). For the ten drugs selected in the first year of this price control program, that will be as early as August 2, 2024.

116. Although the IRA calls it an "excise tax," in reality this imposition is an astronomical daily fine that continues until the manufacturer caves and enters into an "agreement"

[10] In recent guidance, the IRS suggests that the "excise tax" will apply only to sales in connection with federal healthcare programs. *See* I.R.S. Notice No. 2023-52, Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax (Aug. 4, 2023), https://www.irs.gov/pub/irs-drop/n-23-52.pdf. The statute, however, contains no such limitation, and the IRS's guidance is explicitly temporary and non-binding.

with HHS. The "excise tax" starts at a level so high that it amounts to nearly 200% of the drug's pre-tax price. And it increases each quarter until it represents 1900% of the pre-tax price. *Id.* § 5000D(d).

117. Under the convoluted statutory formula, the "excise tax" is "an amount such that the applicable percentage is equal to the ratio of (1) such tax, divided by (2) the sum of such tax and the price for which so sold [*sic*]." *Id.* § 5000D(a). The "applicable percentages" are 65% for the first 90 days of noncompliance, 75% for the next 90 days, 85% for the next 90 days, and 95% for any day after that. *See id.* § 5000D(d). That means, for example, that if a drug is sold for $1.00 and the applicable percentage is 65%, the "tax" is approximately $1.85 (so that the "tax" of $1.85 equals 65% of $2.85, the sum of the "tax" and the "pre-tax" price of the drug). In that instance, the "tax" would be 185% of the "pre-tax" price. If the applicable percentage were 95%, the "tax" would be $19 on a $1 sale ($19 is 95% of $20, the sum of the "tax" and the "pre-tax" price), which represents 1900% of the "pre-tax" price.

118. The "excise tax" can be calculated by setting the statutory formula equal to the "applicable percentage" and then solving for the "tax":

$$\text{applicable percentage} = \frac{\text{tax}}{(\text{tax} + \text{sales price of drug})}$$

For example, using the highest "applicable percentage" (95%), one would solve for the penalty as follows:

$$\textbf{STEP 1}: .95 = \frac{\text{tax}}{(\text{tax} + \text{sales price of drug})}$$

$$\textbf{STEP 2}: \text{tax} = .95\ (\text{tax} + \text{sales price of drug})$$

$$\textbf{STEP 3}: \text{tax} = .95\ (\text{tax}) + .95\ (\text{sales price of drug})$$

$$\textbf{STEP 4}: \text{tax} - .95(\text{tax}) = .95\ (\text{sales price of drug})$$

$$\textbf{STEP 5}: .05(\text{tax}) = .95\ (\text{sales price of drug})$$

$$\textbf{STEP 6}: \text{tax} = \frac{.95\ (\text{sales price of drug})}{.05}$$

$$\textbf{SOLUTION}: \text{tax} = 19\ (\text{sales price of drug})$$

Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 29 (Aug. 10, 2022).

119. This statutory formula means that if a manufacturer refuses to "agree" to the government's demands, the government hits it with penalties up to *19 times* the drug's total sales revenue. *See id.* at 4 tbl. 2. Even the lowest applicable percentage (65%) penalizes a manufacturer nearly double its daily sales revenue from the drug. *See id.* ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance.").

120. Those penalties accrue every day until the manufacturer enters into an "agreement" with HHS, the drug in question ceases to be eligible for "negotiation," or the manufacturer successfully withdraws *all* of its drugs from Medicare and Medicaid. 26 U.S.C. § 5000D(c); *see id*. § 5000D(c)(1) (providing that the penalty is suspended only during a period in which "none of the drugs of the manufacturer . . . are covered by an agreement" under certain programs within Medicare Part D and the manufacturer has given notice of termination of "all applicable agreements"—including agreements necessary for the manufacturer's drugs to be payable under Medicare Part D and Medicaid); 42 U.S.C. § 1396r-8(a)(1) (providing that if a manufacturer terminates a Medicaid rebate agreement, none of the manufacturer's drugs will be covered under Medicare Part B); 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii) (termination of Medicare Part D agreements).

121. The government does not distinguish between members of a corporate family for purposes of participation in Medicare and Medicaid. Indeed, HHS and CMS are in the process of

promulgating a regulation to codify that "longstanding policy." Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 Fed. Reg. 34,238, 34,256 (May 26, 2023). As a result, a manufacturer and its subsidiaries are treated together and are all either "all in" or "all out" of Medicare and Medicaid. In the case of IMBRUVICA®, this means that even if Pharmacyclics withdrew from the requisite federal healthcare programs, AbbVie would still be hit with the IRA's "excise tax." For AbbVie to avoid the "excise tax," not only Pharmacyclics, but also AbbVie (and every other entity in the AbbVie corporate family), would have to withdraw—meaning that not only would IMBRUVICA® no longer be covered, but Medicare and Medicaid beneficiaries would also lose access to all of AbbVie's more than 85 other medicines that are currently covered by those programs.

122. Withdrawing all of a manufacturer's drugs (let alone all of a corporate family's drugs) from federal healthcare programs is not a viable option, for two independent reasons. First, Medicare and Medicaid dominate the healthcare market. In 2021, Medicare, as a single payer, accounted for 21% of national health spending and Medicaid for 17%. By comparison, private health insurance, broken out across thousands of different payers, accounted for, in total, 28% of national health spending. CMS, *NHE Fact Sheet: Historical NHE, 2021*, CMS.gov (Feb. 17, 2023), https://go.cms.gov/41mwXL8. As noted above, Medicare and Medicaid account for more than 60% of all sales of IMBRUVICA®.

123. Courts have long recognized that forcing a regulated entity to choose between two devastating outcomes—"the rock and the whirlpool"—is no real choice at all. *Frost v. R.R. Comm'n*, 271 U.S. 583, 593 (1926). If the government could pressure citizens to give up constitutional rights by withholding valuable benefits, then "constitutional guaranties, so carefully

safeguarded against direct assault," would be "open to destruction by the indirect, but no less effective, process of requiring a surrender, which, though in form voluntary, in fact lacks none of the elements of compulsion." *Id.*

124. The Supreme Court recently applied similar reasoning to a Medicaid funding condition in *National Federation of Independent Business v. Sebelius* ("*NFIB*"), 567 U.S. 519 (2012). There, Congress attempted to force States to accept a Medicaid expansion by threatening the withdrawal of all Medicaid funding. Although the Medicaid expansion may have been "*in form* voluntary," *Frost*, 271 U.S. at 593 (emphasis added), the Court held that "[t]he threatened loss of over 10 percent of a State's overall budget . . . is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion," *NFIB*, 567 U.S. at 582.

125. The IRA's price control program is an even stronger example of economic dragooning. Whereas federal Medicaid funding comprised 10% of the States' budgets in *NFIB*, Medicaid and Medicare account for nearly *half* of the prescription drug market. Congress knew that for a manufacturer to withdraw all of its products from federal healthcare programs would be economic suicide—not a "real option." *NFIB*, 567 U.S. at 582. That is why Congress could enact this scheme without worrying that Medicare beneficiaries would suddenly lose access to needed drugs. And if States, with all the resources they can marshal, are vulnerable to financial coercion, private entities are even more vulnerable to the "ruinous" "loss of federal funds." *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020). Any "asserted power of choice" is "illusory." *United States v. Butler*, 297 U.S. 1, 71 (1936).

126. Second, even if a manufacturer somehow were to conclude that it could afford to withdraw all of its drugs from Medicare Part D and Medicaid, the manufacturer has no legal ability to do so in a timely way to avoid the "excise tax." That is because it takes 11 to 23 months,

depending on the timing during the calendar year, for a notice of withdrawal from the relevant agreements to take effect. For example, with respect to the Medicare Part D Coverage Gap agreement, if the manufacturer provides notice of termination before January 30 of a calendar year, the termination does not become effective until the day after the end of the calendar year (a minimum of 11 months). *See* 42 U.S.C. § 1395w-114a. If the manufacturer provides notice on or after January 30, the termination does not become effective until the day after the next year (as long as 23 months). *Id.* This delayed withdrawal process works the same way with respect to the "manufacturer discount program" agreement created by the IRA itself (except that the date by which the manufacturer must provide notice to avoid a delay spanning multiple calendar years is January 31 instead of January 30). *See* 42 U.S.C. § 1395w-114c. Congress thus adopted a materially identical delayed-withdrawal mechanism when it enacted the IRA, underscoring its intent to prevent manufacturers from escaping the IRA's price controls.

127. In light of that delayed-withdrawal mechanism, even if a manufacturer terminated its Medicare Part D Coverage Gap agreement in June 2023 when this action was filed, that termination would not take effect until January 1, 2025—over a year and half later.

128. But the "excise tax" takes effect much sooner. For drugs selected for "negotiation" for the first year of the program, the "excise tax" kicks in on October 2, 2023, if the manufacturer does not enter into an "agreement" to "negotiate" by the October 1 deadline or submit to the agency by the October 2 deadline all the information, including highly confidential business information, that HHS decides to require.

129. As a result, even if a manufacturer gives "notice of termination[]" of its Medicare Part D Coverage Gap agreement, 26 U.S.C. § 5000D(c)(1)(A)(i), it is trapped: it will have to wait for up to nearly two years before "none of the drugs of the manufacturer of the designated drug

are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act," *id*. § 5000D(c)(1)(A)(ii), and during that lengthy period it remains subject to the "excise tax." The manufacturer thus has no way of avoiding this crippling penalty—other than by "agreeing" to "negotiate," further confirming the involuntary nature of such an "agreement."

130. Congress designed the "excise tax" so that manufacturers would be boxed in, unable to pass the tax along to purchasers (because no one could afford to buy a drug whose purchase price was inflated by a 1900% tax) and unable economically to bear the tax and continue selling the drug (because the accumulated tax burden would devastate any manufacturer). *See* Susan Davis, *Speaker Nancy Pelosi Unveils Plan to Lower Prescription Drug Costs*, NPR (Sept. 19, 2019), https://www.npr.org/2019/09/19/761954160/speaker-nancy-pelosi-to-unveil-plan-to-negotiate-prices-of-250-prescription-drug (noting that a proposal for a predecessor bill included what the proposal called a "steep, escalating penalty" on manufacturers).

131. Nor could Congress have intended to force manufacturers to pull drugs off the market in order to avoid the "excise tax." Drugs subject to the IRA's "negotiation" regime and the "excise tax" will be, by definition, among the most frequently used by Medicare patients. If manufacturers had to stop selling them to avoid the "excise tax," that would be catastrophic for untold numbers of Medicare beneficiaries and their families.

132. Perhaps the clearest proof that the "excise tax" is simply a weapon compelling manufacturers to "agree" to "negotiate" and not a real tax is the recognition of Congress's own budget office that the "tax" would raise precisely zero dollars in revenue. *See* Cong. Budget Off., Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14, at 5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

133. In response to litigation, seemingly recognizing that the statutory 11- to 23-month delays before a termination by a manufacturer can take effect made it impossible to defend the IRA's constitutionality, CMS issued non-binding guidance that purports to rewrite and nullify those statutory provisions. *See* Revised Guidance at 120–21, 129–31.

134. Under the statutes, there are only two distinct pathways for termination—one for termination by the Secretary (for misconduct), and the other for termination by the manufacturer ("for any reason"). *See* 42 U.S.C. § 1395w-114a(b)(4)(B). Under the first provision, when "the Secretary" seeks to terminate a manufacturer for misconduct (*i.e.*, a "knowing and willful violation of the requirements of the agreement or other good cause shown"), the manufacturer has the right to a "hearing" before the effective date of the termination. *Id*. § 1395w-114a(b)(4)(B)(i). In the second provision, Congress spelled out a very different procedure for the very different situation where a manufacturer wishes to terminate its own participation: "a manufacturer" may terminate "for any reason" (and no hearing is provided in such a case), but must wait 11 to 23 months after giving notice. *Id*. § 1395w-114a(b)(4)(B)(ii).

135. The CMS guidance tries to undo Congress's careful dichotomy by stating that it will treat *a manufacturer's* desire to terminate its participation, which Congress decreed would be effectuated through § 1395w-114a(b)(4)(B)(ii), as "good cause" for *CMS* to terminate the manufacturer pursuant to § 1395w-114a(b)(4)(B)(i).

136. That interpretation makes a hash of the statute. The text and structure of the statutory provisions make clear that "good cause shown" under the first provision cannot be so limitless as to include a manufacturer's voluntary termination. Such a broad interpretation would ignore the significance of the "knowing and willful violation" language in the first provision, which circumscribes the meaning of "other good cause shown." *See Sprietsma v. Mercury Marine,*

537 U.S. 51, 63 (2002) ("[A] word is known by the company it keeps" (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995))). Just as important, swallowing voluntary terminations "[b]y a manufacturer" within the first provision would render the second provision "wholly superfluous," *Duncan v. Walker*, 533 U.S. 167, 174 (2001). And the manufacturer's right to a pre-termination "hearing" in the first provision would be doubly superfluous—giving the manufacturer a hearing on *its own* request for termination. Attempting to square that circle, the CMS guidance nonsensically advises both that "it will automatically grant such termination requests upon receipt" and that "CMS shall, upon written request from [the manufacturer], provide a hearing concerning its termination request"—the same request that CMS has just said it will already have automatically granted. Revised Guidance at 121. The knots that CMS has tied itself in are a sure sign that it is taking liberties with the statute.

137. Agencies cannot "rewrite and recast plain statutory text" in this manner. *Citizens for Resp. & Ethics in Washington v. FEC*, 904 F.3d 1014, 1018 (D.C. Cir. 2018) (per curiam). A "core administrative-law principle" is that "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014). To allow an agency to rewrite a statute "would deal a severe blow to the Constitution's separation of powers." *Id.*

138. Manufacturers cannot rely on the CMS guidance because it is contrary to statutes enacted by Congress and because, as a non-binding statement of the agency's current position, it can be changed at any time. As a matter of law, there is no escape from the astronomical "excise tax."

139. Plaintiffs are not aware of any other statute that imposes similarly draconian sanctions on conduct as ordinary as walking away from a "negotiation" that does not result in a

mutually acceptable deal. Refusing to go along with the government's effort to duck political accountability for price controls is not culpable conduct that can justify the imposition of crushing penalties under the Constitution.

140. The Internal Revenue Code (the "Code") imposes excise taxes on sales of many products and substances. Typically, manufacturer excise taxes on sales of products are expressed as a percentage of the subject sales or a fixed amount per sale. *See, e.g.*, 26 U.S.C. §§ 4661 & 4662. For example, the Affordable Care Act initially included an excise tax on the sale of any taxable medical device by the manufacturer or importer of the device. The excise tax was 2.3 percent of the wholesale price of a medical device. *See* 26 U.S.C. § 4191(a). An excise tax that is many multiples of the value of the sale is unprecedented.

141. Nor are there any other statutes of which Plaintiffs are aware that impose penalties—much less crippling penalties on this scale—for mere failure to "agree" to the government's demand in a purported "negotiation." *Cf. Carter v. Carter Coal Co.*, 298 U.S. 238, 288–89 (1936) ("The so-called excise tax of 15 *per centum* on the sale price of coal at the mine, or, in the case of captive coal the fair market value, with its drawback allowance of 13 ½ per cent., is clearly not a tax but a penalty. . . . It is very clear that the 'excise tax' is not imposed for revenue but exacted as a penalty to compel compliance with the regulatory provisions of the act. The whole purpose of the exaction is to coerce what is called an agreement—which, of course, it is not, for it lacks the essential element of consent."); *id.* at 286–87 (noting that company's board of directors had decided to "accept the code provided for by the act," even though "it believed the act to be unconstitutional and economically unsound, . . . because the penalty in the form of a 15 per cent. tax on its gross sales would be seriously injurious and might result in bankruptcy").

142. Comparing the IRA's "excise tax" to others under the Code makes clear that the IRA adopts a highly unusual structure that resembles a strict liability fine or penalty, not a tax.

v. Limits on judicial and administrative review

143. Congress went to great lengths to insulate HHS's price control program from administrative and judicial review. Section 1320f-7 provides that there shall be "no administrative or judicial review" of the agency's key determinations regarding which drugs will be swept into the price control program or of the prices set by the agency, namely:

a. "The determination of a unit, with respect to a drug or biological product;"

b. "[t]he selection of drugs under section 1320f-1(b);"

c. "the determination of negotiation-eligible drugs under section 1320f-1(d);"

d. "the determination of qualifying single source drugs under section 1320f-1(e);"

e. "[t]he determination of a maximum fair price under subsection (b) or (f) of section 1320f-3;"

f. "[t]he determination of renegotiation-eligible drugs under section 1320f-3(f)(2);" and

g. "the selection of renegotiation-eligible drugs under section 1320f-3(f)(3)."

144. The IRA combines that curtailment of back-end judicial review with an utter dearth of meaningful input on the front end. The IRA fails to afford manufacturers notice or opportunity to be heard regarding key decisions that HHS will make in implementing the IRA. Instead, the IRA directs HHS to "implement" the entire "negotiation" process "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note. And, as noted, CMS has already resolved critical issues about how it will implement the price control program—including the fundamental issues going to which drug products will be "selected" for "negotiation"—without allowing any public input whatsoever.

vi. Compelled speech

145. The IRA not only limits what prices companies can charge; it adds insult to injury by forcing them to "agree" to prices set by the government that the government publishes as the "maximum fair price." *Id.* § 1320f(d)(1).

146. Manufacturers do not agree with these inaccurate, self-serving characterizations by the government. Yet they are forced to assent to and parrot the government's viewpoint or pay a crippling fine.

147. As explained, if a manufacturer refuses to enter into an "agreement" to "negotiate" with HHS, or if a manufacturer refuses to "agree" to the "maximum fair price" set by HHS, the manufacturer is effectively prohibited from selling its drug—to anyone, not just in government healthcare programs—by the crushing "excise tax." *See* 26 U.S.C. § 5000D. By forcing manufacturers to pretend to "agree" that the IRA's "negotiation" is a genuine negotiation and that HHS's chosen price is the "maximum fair price," Congress conscripted manufacturers to aid its effort to hide the reality that HHS is imposing price controls.

148. Tellingly, CMS's initial guidance proposed a gag order that purported to prohibit manufacturers from telling the truth about the "negotiations." Initial Guidance at 30. This speech ban would have reinforced the statute's compelled-speech requirements by preventing manufacturers from explaining what actually happened in the so-called "negotiations" and from exposing government abuses. Indeed, the provision went so far as to require manufacturers to destroy the evidence of what actually happened during the "negotiations." Although CMS withdrew this "gag order" provision in its revised guidance, the fact that CMS contemplated banning speech about matters of obvious public concern is a sure sign that it knows that its phony "negotiation" regime cannot withstand the light of day and that it needs manufacturers to publicly toe the party line.

149. CMS also tried to paper over the IRA's First Amendment problems in its template manufacturer "agreement." For example, seemingly recognizing that it is unconstitutional to compel manufacturers to endorse CMS's prices as "fair," CMS included the following disclaimer: "In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." Template "Agreement" at 4. But no matter what CMS may say, manufacturers are still compelled by statute to "agree" to the Secretary's so-called "maximum fair price." CMS's crafted-for-litigation disclaimer only underscores that basic reality.

III. The IRA's Far-Reaching Consequences

150. That the IRA tries to strip away judicial, administrative, and even public oversight is no surprise: from top to bottom, the IRA is designed to camouflage and insulate the government from accountability for its massive experiment in central planning and socialized medicine—and for the dramatic consequences it will have for the American people.

151. As the Supreme Court has explained, when the federal government acts for itself, "[v]oters who like or dislike the effects of the regulation know who to credit or blame." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1477 (2018). When the government instead commandeers others to carry out its policies, "responsibility is blurred" and "political accountability" suffers. *Id.*

152. The IRA's deceptions are designed to shield the government from criticism by obfuscating who is responsible for its policies and what the true nature of those policies is: price

controls that will severely undermine the market-based incentives and patent protections that have long driven American pharmaceutical innovation and enhanced patient access to new medicines.

153. Pharmaceutical companies in the United States currently have thousands of drugs under development, most of which are intended to treat severe illnesses like Alzheimer's, cancer, and communicable diseases, including COVID-19.[11] As a result of the IRA and the diminished ability of manufacturers to recoup their investments, continued research and development of many of these potential treatments will no longer be economically viable. The result will be fewer life-saving and life-enhancing drugs for patients in need.[12]

154. Already, in fact, pharmaceutical manufacturers have been forced to cancel potentially promising research and development efforts because of the economic impact of the IRA.[13]

155. Nor will the IRA succeed in its ostensible goal of reducing healthcare costs. Because drugs are often less expensive than other types of treatments, the IRA will likely increase overall healthcare costs.[14]

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[11] Ezell, Ensuring U.S. Biopharmaceutical Competitiveness, *supra* note 4, at 5.

[12] Tomas J. Philipson & Troy Durie, Issue Brief: The Evidence Base on the Impact of Price Controls on Medical Innovation (Sept. 14, 2021), https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Price-Controls-and-Drug-Innovation-Philipson.pdf (University of Chicago study of previous version of IRA); Joel Zinberg, *A Destructive Piece of Legislation*, City J. (Aug. 11, 2022), https://www.city-journal.org/inflation-reduction-act-needless-health-care-provisions.

[13] Josh Nathan-Kazis, *Novartis CEO: Some Cancer Drugs Dropped From Pipeline Because of Medicare Price Negotiations*, Barron's (May 19, 2023), https://www.barrons.com/articles/novartis-stock-price-ceo-cancer-drug-medicare-e9b0fcb7; Reuters, *Roche: Have Abandoned Some Trials Due to U.S. Drug Pricing Plans* (July 27, 2023), https://www.usnews.com/news/us/articles/2023-07-27/roche-have-abandoned-some-trials-due-to-u-s-drug-pricing-plans#:~:text=FRANKFURT%20(Reuters)%20%2DRoche%20said,medicines%20in%20the%20United%20States; Angelica Peebles, *Alnylam Halts Work on Eye Drug, Citing New US Law Over Pricing*, Bloomberg (Oct. 27, 2022), https://www.bloomberg.com/news/articles/2022-10-27/alnylam-halts-work-on-eye-drug--citing-new-us-law-over-pricing.

[14] Stephen Moore & Tomas J. Philipson, *Fewer Cures, Costlier Energy*, Wall St. J. (Aug. 7, 2022), https://www.wsj.com/articles/fewer-cures-costlier-energy-inflation-reduction-act-pharmaceutical-industry-drug-development-disease-cancer-alzheimers-parkinsons-epilepsy-treatments-11659886931.

156. Congress deliberately structured the IRA to maximize the government's power while obscuring the reality of its price controls and dodging accountability for these grave harms to the public interest. This statute is an unprecedented and unlawful power grab.

CLAIMS FOR RELIEF

COUNT 1
(SEPARATION OF POWERS)

157. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

158. The IRA centralizes vast, unreviewable power in the hands of an administrative agency, without the ordinary protections of due process, to decide the fate of the $600 billion pharmaceutical industry and of every American who relies on it.

159. No principle is more central to the design of the Constitution than the separation of powers.

160. Article I of the Constitution vests "[a]ll legislative Powers" in the "Congress of the United States." U.S. Const. art. I, § 1. Article II vests the executive power—the power to implement the laws—in the President. And Article III vests the judicial power—the power to interpret the laws—in the courts.

161. To protect that fundamental separation of powers, the Supreme Court has long distinguished between certain "important subjects, which must be entirely regulated by the legislature itself" and "those of less interest," as to which Congress may afford the executive branch discretion "to fill up the details." *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42–43 (1825).

162. The Supreme Court has accordingly invalidated statutes that confer "virtually unfettered" discretion on the executive branch to control broad swaths of the private economy. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935) (invalidating delegation

to create code of industrial conduct that fosters "fair competition"); *see also Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935) (invalidating delegation to ban petroleum shipments in excess of state production quotas).

163. In *Schechter Poultry*, the Court emphasized the lack of "judicial review to give assurance that the action of the commission is taken within its statutory authority" and the absence of "appropriate administrative procedure" to ensure due process. 295 U.S. at 533, 541. In *Panama Refining*, the Court highlighted the failure to constrain the executive branch with any "standard or rule" of decision. 293 U.S. at 418.

164. Under the Supreme Court's modern precedents, a statutory delegation is invalid if it fails to constrain the agency with an "'intelligible principle.'" *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality op.) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)). This "intelligible principle" must at least be "sufficiently definite and precise to enable Congress, the courts and the public to ascertain whether the [agency] . . . has conformed" to Congress's direction. *Yakus v. United States*, 321 U.S. 414, 426 (1944).

165. Courts have also consistently recognized that "judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." *United States v. Garfinkel,* 29 F.3d 451, 458–59 (8th Cir. 1994) (quoting *United States v. Bozarov*, 974 F.2d 1037, 1042 (9th Cir. 1992)) (collecting cases). Similarly, "compliance with . . . requirements for notice and comment" enhances public accountability and thereby functions as a check on agency discretion. *Id.*; *cf. Panama Ref. Co*., 293 U.S. at 415 (noting the importance of written findings).

166. This tradeoff between delegation and accountability is the basic compromise at the heart of American administrative law. Ordinarily, when Congress gives an agency substantial discretion to restrict private rights—such as the right to sell lawful goods or services at market

rates—it provides certain safeguards to ensure accountability, rationality, and fairness in agency decision-making. These checks and balances include discernible legal standards, formalized opportunities for public input, and—especially—judicial review. Such checks and balances are not merely a matter of legislative grace; they are constitutionally required.

167. Conversely, a lack of due process protections exacerbates the separation-of-powers concerns raised by a broad administrative delegation.

168. For example, in the context of rate-setting for energy transmission, rates must be, at the very least, "just and reasonable," 16 U.S.C. § 824d, and a body of law has been developed to ensure that there is adequate review of the Federal Energy Regulatory Commission's rate-setting authority so that it is not used in an arbitrary or discriminatory manner, which would be unconstitutional. *See, e.g.*, *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968). Statutory procedures limit FERC's authority to set rates and provide opportunities for public hearings. *See* 16 U.S.C. §§ 824d, 824e, 825*l*; *see Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 218 (1991) (noting use of notice-and-comment rulemaking to "revise the old gas pricing system"). And importantly, judicial review is available to ensure that rates set by FERC are consistent with due process, the standard prescribed by Congress, and the procedural requirements of both the governing statute and the APA. *See*, *e.g.,* 15 U.S.C § 717r; 16 U.S.C. § 825*l*.

169. Despite the IRA's breathtaking delegation of power to HHS, the statute lacks both the requisite "intelligible principle" and the constitutional safeguards necessary to ensure accountability, rationality, and fairness. This combination of sweeping power and the total lack of procedural protections is unique and unprecedented.

170. "[L]ack of historical precedent" is "[p]erhaps the most telling indication of [a] severe constitutional problem." *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010) (quotation marks omitted).

171. There can be no doubt about the extraordinary scope of the Secretary's power to abrogate private rights under the IRA. Apart from a temporary price floor for certain small biotechnology manufacturers, 42 U.S.C. § 1320f-3(b)(2)(F)(ii), the IRA imposes only a *ceiling* for its "negotiations." That ceiling ranges from 75% down to 40% of the 2021 non-federal average manufacturer price. *Id.* §§ 1320f-3(c)(1)(C), 1320f-3(b)(2)(F). Congress thus gave HHS "unfettered" discretion to set prices, including at unfairly low, confiscatory levels, without any judicial oversight. *Schechter Poultry*, 295 U.S. at 542. Congress, in other words, did not even gesture at the constitutional necessity of protecting against confiscatory price controls and takings of private property without just compensation.

172. What makes the delegation here especially egregious is the lack of countervailing procedural safeguards. The most basic requirement of the nondelegation doctrine is that Congress "provide[] an administrative agency with standards guiding its actions such that a court could ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989) (quotation marks omitted). As the Supreme Court has explained in other contexts, the "just and reasonable" standard is not merely an accident of congressional drafting; that statutory rule "'coincides' with the applicable constitutional standards." *In re Permian Basin Area Rate Cases*, 390 U.S. at 770 (quoting *FPC v. Nat. Gas Co.*, 315 U.S. 575, 586 (1942)).

173. Here, Congress provided no legal standard at all. Although Congress listed several "factors" for HHS to "consider," 42 U.S.C. § 1320f-3, CMS has acknowledged that the IRA "does not specify how CMS should determine an initial offer nor how or to what degree each factor

should be considered." Initial Guidance at 47; *see* Revised Guidance at 144. And it is well-established that an administrative agency cannot cure a statute's nondelegation problem by promulgating rules or guidance; that would prove, rather than cure, the nondelegation violation. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472–73 (2001).

174. Moreover, those price control factors are merely window-dressing because the IRA precludes both administrative and judicial review of HHS's key determinations, including the selection of drugs for price controls and the determination of the so-called "maximum fair price." *See* 42 U.S.C. § 1320f-7. Thus, as in *Panama Refining*, the executive is effectively unconstrained by any "standard or rule." 293 U.S at 415, 418.

175. Nor does the IRA provide formalized opportunities for public input, such as hearing procedures or notice-and-comment rulemaking. The sham "negotiation" process provides only the appearance of an opportunity to be heard, without any mechanism for ensuring that the agency listened.

176. As illustrated by CMS's radical redefinition of what constitutes a single "drug" for purposes of the IRA—which CMS finalized in a purported "guidance" document without taking comment from the public—CMS has taken, and will continue to take, full advantage of all this unchecked discretion.

177. Congress not only failed to provide the traditional checks and balances; as discussed above, Congress went out of its way to insulate the IRA's drug pricing regime from public accountability by camouflaging its delegation of unbridled regulatory power in novel and insidious ways.

178. This series of optical illusions includes the sham "negotiation" process that, on examination, bears no resemblance to any genuine negotiation; the "maximum fair price"

provisions that require manufacturers to endorse the government's fiction that they are "agreeing" to a price both parties consider "fair"; the punitive and misnamed "excise tax" that is so draconian not even the government expects it to produce any revenue; and the toothless "factors" for the Secretary's consideration, which the Secretary can weigh however he or she likes without any administrative or judicial review. These various ruses are intended to lull onlookers with the *appearance* of a fair, voluntary "negotiation" process, but they are really just a façade for an unprecedented regime of extreme, unchecked delegation of power from Congress to the Executive, to be administered without standard protections against error and without judicial review of the results.

179. Each of these defects would be troubling and constitutionally suspect in its own right. Taken together, the combination of sweeping delegation with a total lack of corresponding safeguards creates an unconstitutional anomaly—an unaccountable structure that has slipped the bounds of the separation of powers. *See Schechter Poultry*, 295 U.S. 495; *Panama Refining*, 293 U.S. 388; *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2201–04 (2020); *Free Enter. Fund*, 561 U.S. at 495–98, 505.

180. Even worse, Congress delegated such unbridled power to the Secretary for no legitimate reason. Congress had no need to create a sham "negotiation" process or to compel manufacturers to voice the government's party line by pretending that they are "agreeing" that the price set by HHS is the "maximum fair price"; Congress could have owned up to the fact that it was creating a price control regime. And Congress had no need to bar all judicial review of the agency's decisions; other price control regimes have operated with judicial review to ensure that the prices set are fair and non-discriminatory.

181. The only plausible explanation for the way the IRA is structured is that the President and Members of Congress thought that it would be easier and more politically palatable to enact a price control program designed to reshape the nation's prescription drug markets by advertising it as a "negotiation" program and by guarding it against judicial scrutiny, even though doing so violated the Constitution. Whatever the precise motivations for individual members, the program created here does not comport with basic constitutional limits. Instead, it turns the separation of powers on its head by giving the Executive unchecked power without an intelligible principle to guide it and without judicial review to confine it.

COUNT 2
(DUE PROCESS)

182. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

183. The Fifth Amendment's Due Process Clause prohibits the government from depriving a person of property without adhering to constitutionally sufficient procedures. *See Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 460 (1989).

184. At its core, the Due Process Clause requires notice and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965); *see also Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Due process requires procedural protections to prevent, to the extent possible, an erroneous deprivation of property. *See Gilbert v. Homar*, 520 U.S. 924, 930–32 (1997).

185. Pharmaceutical manufacturers have constitutionally protected property interests in their drugs, their investment-backed patent rights, and their investment-backed expectations to be free from price controls that are "arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt." *In re Permian Basin Area Rate Cases*, 390 U.S. at 769–70 (quoting *Nebbia v. New York*, 291 U.S. 502, 539 (1934)). The IRA seeks to deprive manufacturers of those

property interests by directing the Secretary to fix prices at the "lowest" level, without adequate procedural safeguards.

186. Despite the magnitude of the IRA's delegation to HHS, the IRA affords manufacturers no guarantee that they will have an opportunity to be heard on the key decisions that HHS will make. CMS has already made clear that it will not engage in notice-and-comment rulemaking, and it has even denied manufacturers the opportunity to provide public comment of any kind on its guidance regarding drug selection. Initial Guidance at 2. And far from attempting to make up for this lack of front-end procedural protections by prescribing rigorous back-end judicial review, the IRA expressly deprives manufacturers of any judicial review of HHS's key decisions.

187. In the context of administrative price controls, courts have long recognized constitutional limits on the government's rate-setting authority designed to protect against arbitrary and confiscatory government action.

188. Due process requires at minimum an enforceable legal standard to ensure "just and reasonable" prices. *See Mich. Bell Tel. Co. v. Engler,* 257 F.3d 587, 592–93 (6th Cir. 2001). A "just and reasonable" price is one that not only covers the company's costs but allows it to earn "a fair and reasonable rate of return on investment." *Id.* at 594.

189. Even when it comes to public utilities—which, unlike pharmaceutical manufacturers or nearly all other types of companies, have traditionally been required to serve the public on heavily regulated terms—the Constitution "protects utilities from being limited to a charge for their property serving the public which is so 'unjust' as to be confiscatory." *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989); *see Nat. Gas Pipeline Co.*, 315 U.S. at 585.

190. Manufacturers are unable to avoid the harms associated with the IRA's deprivation of their property interests by refusing to participate in government healthcare programs.

191. As explained above, withdrawing from Medicare and Medicaid is not a practicable option for manufacturers. In any event, even if a manufacturer were economically able to withdraw, it would be legally unable to accomplish that withdrawal in time to avoid the "excise tax," because withdrawing from Medicare Part D can take up to 23 months. *See* 42 U.S.C. § 1395w-114c(b)(4)(B)(ii). As a result, the manufacturer will be compelled to "agree" to whatever price the Secretary declares is the "maximum fair price," since the alternative is to be effectively prohibited from selling the drug at all by having to increase its price by up to 19 times because of the "excise tax." *See* 26 U.S.C. § 5000D(c)(1).

192. Therefore, there is no way a manufacturer could avoid the imposition of the "excise tax" for the 2026 price applicability year other than to "agree" to "negotiate" by October 1, 2023.

193. Even setting aside the problem of how long it would take for a manufacturer to withdraw all of its drugs from Medicare and Medicaid, the IRA's requirement that a manufacturer must do so to avoid the "excise tax" is a severe and "coerc[ive]" consequence in itself. *NFIB*, 567 U.S. at 585.

194. As discussed above, compelling manufacturers to submit to the IRA's price-control program or withdraw all of their products from the federal health care programs, which account for nearly half of the relevant market, is impermissible "economic dragooning." *Id.* at 582. Manufacturers have "no real option" regarding whether to participate in programs that are vital to their livelihoods. *Id.*

195. It is well-established that "even though a person has no right to a valuable governmental benefit and even though the government may deny him the benefit for any number

of reasons, there are some reasons upon which the government may not rely." *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434–36 (6th Cir. 2005) (quotation marks omitted). The government may not "condition[] benefits on a citizen's agreement to surrender due process rights." *Id.*

196. The IRA is also poised to take away one of the most important components of the bundle of rights conveyed to a manufacturer when it pioneers and patents a novel drug: the right to determine the price of the drug for the duration of its patent exclusivity (and beyond).

197. A patent "confers upon the patentee an exclusive property in the patented invention." *Horne v. Dep't of Agric.*, 576 U.S. 350, 359 (2015) (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)). Thus, when a manufacturer obtains a patent for a novel drug, it is the only one who can sell that drug for the term of the patent. The market ordinarily sets the price for that patented product. *See King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) ("Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.").

198. Manufacturers rely on the promise of future sales—and the ability to set the price for their products in the marketplace—when developing and patenting a drug. *See id.*

199. The IRA undermines manufacturers' rights by severely limiting their ability to recoup investments. More broadly, the law disrupts manufacturers' reasonable investment-backed expectations that they will be able to sell their drugs at a reasonable price, particularly in light of their drugs' patent exclusivities.

200. When evaluating whether the government has afforded constitutionally adequate procedures before depriving a person of a protected property interest, courts often evaluate "three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable

value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976)).

201. The IRA fails all three *Eldridge* factors.

202. *First*, the private interests that will be affected by the Secretary's price controls are enormous. There is no scenario under the IRA in which manufacturers will not suffer significant losses, as even the IRA's ceiling for "negotiations" is already far below market prices and the IRA directs the Secretary to "aim[] to achieve the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added). And imposing heavy losses on pharmaceutical manufacturers means that they will have fewer resources to invest in innovation in life-saving and life-enhancing medications for all of us.

203. *Second*, erroneous deprivations are virtually guaranteed since the IRA provides no procedures to protect against them. The IRA tasks the Secretary with "develop[ing] and us[ing] a consistent methodology and process," but the only goal the IRA prescribes is "to achieve the lowest maximum fair price." *Id*. The IRA also removes any mechanism to police whether the Secretary actually creates and conforms to such a process because the IRA strips manufacturers of the right to administrative or judicial review.

204. Indeed, while a "maximum fair price" set so low as to be confiscatory would be "erroneous" in the constitutional sense—it would effect a taking and a violation of the substantive component of the Due Process Clause—the combination of the unreasonably low statutory ceiling, the lack of a statutory floor, Congress's directive to the Secretary to "achieve the lowest maximum fair price," and the numerous provisions barring administrative and judicial review suggests that

unconstitutionally confiscatory and arbitrary prices may be exactly what the IRA is intended to produce.

205. Even if the IRA is not specifically intended to produce prices so low as to deprive manufacturers of their property without due process of law, the IRA's design creates a very high risk of that result. Congress, after all, failed even to legislate a basic standard for HHS to apply. If an agency is required by statute to set prices that are "just and reasonable," and if the statute provides for fair procedures to inform and scrutinize the agency's decision-making, the agency is more likely to set prices that are, in fact, just and reasonable—rather than unjust and confiscatory. But the "just and reasonable" standard, so ubiquitous elsewhere when the government sets prices, is conspicuously absent from the IRA.

206. In keeping with Congress's failure to legislate a standard for HHS to apply, the IRA gives the Secretary no guidance about how to formulate the government's "offer" or about when the manufacturer's "counteroffer" should be accepted or rejected. Nor does the IRA require, or even contemplate, that HHS will engage in rulemaking to clarify these critical questions. To the contrary, Congress decreed that HHS is to implement the program "by program instruction or other forms of program guidance"—meaning that, so far as the IRA is concerned, HHS can dispense with even receiving input from regulated parties, and implying that HHS may ignore any such input that it may receive. *Id*. § 1320f note.

207. The statute also bars review of many of HHS's critical decisions. Congress provided that "[t]here shall be no administrative or judicial review" of "the determination of negotiation-eligible drugs," "[t]he selection of drugs," or "[t]he determination of a maximum fair price under [the Act]." *Id*. § 1320f-7(2)–(3).

208. Congress's insistence on making the Secretary's price control regime a black box means that manufacturers not only are likely to face "maximum fair prices" that are unfairly low and arbitrary, but that they are also at great risk of discrimination as against other manufacturers. Without a legal standard cabining the Secretary's price-setting discretion, and without judicial review to shine a light into the agency's decision-making, the Secretary is free, as far as the IRA is concerned, to pick and choose which manufacturers to disadvantage with especially low "maximum fair prices."

209. Indeed, arbitrary differences between manufacturers are practically inevitable given the lack of any legal standard, transparent procedures, or judicial review.

210. By dispensing with notice-and-comment rulemaking, failing to legislate any price-setting standard (other than "lowest"), failing to create any transparent procedures for the "negotiation" process, and barring judicial review of the Secretary's key decisions, Congress has created an unprecedentedly arbitrary regime. Given the weighty private interests at stake, any one of these defects would create a serious due process problem. In combination, they reveal the IRA's price control program for what it is: an indefensible effort by Congress to direct HHS to deprive manufacturers of property without fair procedures while keeping the public in the dark about the true nature of this regime.

211. *Third*, the government has no legitimate interest in setting up all these roadblocks. Shielding HHS from input from the public, authorizing it to set prices as low as it wants, and shielding it from judicial review may discourage public criticism of HHS's actions. But that is only because these roadblocks will make it harder for the public to understand what the government is up to. The Due Process Clause requires more before an agency can create an

entirely new price control regime that runs counter to a lifetime of statutory precedent and that will impose billions of dollars in losses on one of our nation's critical industries.

212. The IRA's drug price control program is therefore unconstitutional under the Fifth Amendment and must be enjoined.

COUNT 3
(EXCESSIVE FINES CLAUSE)

213. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

214. The Eighth Amendment bars the imposition of "excessive fines"—grossly disproportionate monetary exactions that are designed, at least in part, to serve a punitive purpose. *Austin v. United States*, 509 U.S. 602, 609–10 (1993).

215. The Supreme Court has explained that the Excessive Fines Clause "limits the government's power to extract payments, whether in cash or in kind 'as *punishment* for some offense.'" *Id.* (quoting *Browning-Ferris Indus of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 265 (1989))

216. Whether civil or criminal, a fine is unconstitutional under the Eighth Amendment when the amount is grossly disproportionate to the gravity of the conduct it is designed to punish.

217. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: the amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998) (citing *Austin*, 509 U.S. at 622–23); *Collins v. SEC*, 736 F.3d 521, 526 (D.C. Cir. 2013).

218. In distinguishing taxes from penalties, the Supreme Court has adopted a "functional approach." *NFIB*, 567 U.S. at 565. Courts consider the substance of the imposition and not the label assigned by Congress; whether Congress calls it a "tax" is irrelevant. *See Dep't of Revenue v. Kurth Ranch*, 511 U.S. 767, 775 (1994) ("That the assessment is called a tax, as opposed to some

kind of penalty, is not controlling"). When evaluating the substance of the exaction, courts look at both the size and purpose to evaluate whether it is punitive. *See id.* at 780; *Dye v. Frank*, 355 F.3d 1102, 1105 (7th Cir. 2004).

219. Courts look at whether the fine is levied at a "remarkably high" rate. *Kurth*, 511 U.S. at 780. Relatedly, they also consider whether a so-called "tax" is intended to punish or deter certain conduct rather than merely compensate the government fairly for actual losses. *See Austin*, 509 U.S. at 610–11 (explaining that a civil sanction is beyond the purview of the Excessive Fines Clause only if it has a "solely . . . remedial purpose").

220. Here, the IRA's "excise tax" is designed for the obvious purpose of forcing manufacturers to "agree" to the price mandated by the government. *See Carter Coal Co.*, 298 U.S. at 310 ("That the act, whatever it may be in form, in fact is compulsory clearly appears. We have already discussed § 3, which imposes the excise tax as a penalty to compel 'acceptance' of the code.").

221. Regardless of its name, the IRA's "excise tax" is a penalty. The excise tax punishes manufacturers that refuse to "agree" to "negotiate" or to "agree" to the "maximum fair price" dictated by the Secretary by making it effectively impossible for the manufacturer to continue selling the drug at issue.

222. Some excise taxes are designed to discourage use of the product at issue. But this misnamed "excise tax" is not: Congress could not have intended to discourage patients who need these drugs from obtaining them. If companies had to stop selling the drugs at issue in order to avoid the "excise tax," that would be catastrophic for untold numbers of Medicare beneficiaries and their families.

223. Some excise taxes are designed to raise revenue. But this misnamed "excise tax" is not: Congress's own budget office recognized that it would raise no revenue whatsoever because no one could afford to pay it.

224. These features make the "excise tax" a textbook "penalty with the characteristics of regulation and punishment" that violates the Constitution because it is grossly out of proportion to the "offenses" that trigger the fine. *NFIB*, 576 U.S. at 572–73 (noting that Congress's taxing power "is not without limits" and "'there comes a time in the extension of the penalizing features of the so-called tax when it loses its character as such and becomes a mere penalty with the characteristics of regulation and punishment'" (quoting *Kurth Ranch*, 511 U.S. at 779)).

225. The penalty is grossly disproportionate to the culpability of the conduct that it punishes. The penalty can amount to 1900% of the total daily revenues for all sales of the relevant drug. Plaintiffs are not aware of any other statute that imposes similarly severe sanctions on comparable behavior. The "excise tax" can even be triggered by merely failing to submit information that the Secretary deems "necessary" in whatever timeframe the Secretary demands. 26 U.S.C. § 5000D(b)(1)–(4).

226. Unlike with most penalties, no "reprehensible" offense is being punished here. *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 432, 435 (2001). A manufacturer that refused to "agree" to "negotiate" or to "agree" that the Secretary's chosen price is the "maximum fair price" would not be engaging in any reprehensible conduct at all. *Cf. BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 576 (1996) (indicating that "violence or the threat of violence," "trickery," "deceit," and "indifference to or reckless disregard for the health and safety of others" are "aggravating factors associated with particularly reprehensible conduct" (quotation marks omitted)).

227. In sum, because the IRA's severe and escalating "excise tax" penalty is grossly disproportionate to the conduct at issue, it violates the Excessive Fines Clause and must be enjoined.

COUNT 4
(NO LEGISLATIVE AUTHORITY)

228. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

229. The IRA's so-called "excise tax" is unauthorized by any power of Congress.

230. Under the Constitution, the federal government is a government of "limited and enumerated powers." *Alden v. Maine*, 527 U.S. 706, 713 (1999).

231. Any powers not expressly delegated to the federal government are reserved to the States, as embodied in the Tenth Amendment, or to the people themselves, as embodied in the Ninth Amendment. As Justice Story explained, "[b]eing an instrument of limited and enumerated powers, it follows irresistibly, that what is not conferred, is withheld, and belongs to the state authorities, if invested by their constitutions of government respectively in them; and if not so invested, it is retained by the people, as a part of their residuary sovereignty." 3 Joseph Story, Commentaries on the Constitution of the United States § 1900 (1833).

232. Article I sets forth the enumerated powers of Congress. It provides that "[a]ll legislative Powers *herein granted* shall be vested in a Congress of the United States." U.S. Const. art. I (emphasis added).

233. None of the powers enumerated in Article I authorizes Congress to impose a phony "excise tax" on private companies to force them to "agree" to subject themselves to government price controls disguised as "negotiations" or to "agree" to whatever rock-bottom price the Secretary dictates.

234. The "excise tax" is not authorized by Congress's taxing power because it is a penalty, not a true tax. The Taxing Clause provides that Congress may "lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States." Art. I, § 8, cl. 1.

235. As the Supreme Court has recognized, Congress's "ability to use its taxing power to influence conduct is not without limits." *NFIB*, 567 U.S. at 572. "[T]here comes a time in the extension of the penalizing features of the so-called tax when it loses its character as such and becomes a mere penalty with the characteristics of regulation and punishment.'" *Id*. at 573 (quoting *Kurth Ranch*, 511 U.S. at 779).

236. The "essential feature of any tax" is that "[i]t produces at least some revenue for the Government." *Id.* at 564; *accord Liberty Univ., Inc. v. Lew*, 733 F.3d 72, 97 (4th Cir. 2013). A true tax, unlike a penalty, also does not "impose[] an exceedingly heavy burden." *NFIB*, 567 U.S. at 565.

237. Congress's own budget office has effectively acknowledged that the IRA's "excise tax" is so punitive that it is not expected to produce *any* revenue whatsoever. And there can be no dispute that a tax of up to 1900% imposes "an exceedingly heavy burden." *See id.* (describing a 10% tax on a company's net income as an "exceedingly heavy burden").

238. Nor can the "excise tax" be justified as an exercise of the commerce power. *See* Art. I, § 8, cl. 3.

239. "The Framers gave Congress the power to *regulate* commerce, not to *compel* it." *NFIB*, 567 U.S. at 555 (emphasis in original). "[F]or over 200 years both [the Court's] decisions and Congress's actions have reflected this understanding." *Id.*

240. The IRA's astronomical "excise tax" compels commerce by forcing manufacturers to "agree" to sell their products at the government's unilaterally imposed prices. The IRA does not merely forbid manufacturers from selling their drugs at a price higher than the one the government decides is the "maximum fair price"; it requires manufacturers to "agree" to "provide access" to the "maximum fair price" to "maximum fair price eligible individuals." 42 U.S.C. § 1320f-2(a)(1), (2), (3).

241. By requiring manufacturers to affirmatively provide access to their drugs at the government's chosen price, the IRA's "agreement" and "negotiation" provisions effectuate a compelled transfer of manufacturers' property. *See Horne,* 576 U.S. at 359, 360 ("Nothing in [Anglo-American] history suggests that personal property was any less protected against physical appropriation than real property"). While Plaintiffs' members therefore may pursue individual takings claims, the critical point for purposes of Plaintiffs' enumerated powers challenge to the IRA's "excise tax" is that it purports to require manufacturers to engage in commercial activity that manufacturers do not want to engage in. As with the private citizens who objected to purchasing health insurance in *NFIB*, it is manufacturers' "*failure*" to engage in commercial activity that triggers the penalty. 567 U.S. at 547 (emphasis added).

242. The Supreme Court's Commerce Clause cases "uniformly describe the power as reaching 'activity.'" *Id.* at 551 (collecting cases). Like the failure to *buy* a product or service, the failure to *sell* a product or service is "inactivity," not "activity."

243. To avoid the IRA's crippling penalties, manufacturers must take the affirmative acts of "agreeing" to "negotiate" with the government and then "agreeing" to provide their drugs to government healthcare programs at whatever price the Secretary chooses.

244. Although Congress framed the "excise tax" as a tax on "sales," Congress cannot expect any sales actually to occur under the crushing weight of the so-called tax. In reality, then, the "excise tax" is a massive penalty for a manufacturer's noncompliance with the IRA—*i.e.*, its failure to sell its property on the government's terms, no matter how confiscatory and unfair.

245. The "excise tax" is not authorized by any other enumerated power of Congress.

246. Because the IRA's "excise tax" is not authorized by any enumerated power of Congress, it must be enjoined.

COUNT 5
(FIRST AMENDMENT)

247. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

248. The First Amendment provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. 1.

249. The First Amendment protects not only the right to say what one believes, but also the right to *avoid* conveying a message that one does *not* believe. *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). "If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in . . . matters of opinion or force citizens to confess by word or act their faith therein." *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

250. The First Amendment accordingly prohibits the government from compelling private businesses to espouse the government's favored viewpoints.

251. Compelled speech is often even more objectionable than censorship because those who are forced to speak are "coerced into betraying their convictions." *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018). For that reason, "a law commanding 'involuntary affirmation' of objected-to beliefs . . . require[s] 'even more immediate and urgent

grounds' than a law demanding silence." *Id.* (quoting *Barnette*, 319 U.S. at 633). Such laws, which trigger strict judicial scrutiny, are "presumptively unconstitutional" and must be "narrowly tailored to serve compelling [government] interests.'" *Nat'l Inst. of Fam & Life Advocs. v. Becerra* (*NIFLA*), 138 S. Ct. 2361, 2371 (2018) (quoting *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015)).

252. It is one thing for the government to cap prices for a private company's goods or services. It is another for the government to force that company to pretend that it "agreed" to those prices and to endorse those prices as the "maximum fair price"—implying not only that the Secretary's price is "fair," but that no price higher than the Secretary's price could also be fair. The companies do not agree with these inaccurate, self-serving characterizations by the government. Yet they are forced to endorse the government's viewpoint. That "involuntary affirmation" is compelled speech. *Barnette*, 319 U.S. at 633.

253. This compelled-speech regime cannot satisfy any level of First Amendment scrutiny, let alone strict scrutiny.

254. The government has "no legitimate reason," much less a compelling one, to force businesses to convey a false or misleading statement. *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Ent. Merchants Ass'n*, 564 U.S. 786 (2011). That is especially so where, as here, the deception is designed to shield the government from criticism by obscuring who is responsible for its policies and what the true nature of those policies is. And while the government might wish to disseminate its views about issues such as what drug prices are fair, "where the State's interest is to disseminate an ideology . . . such interest cannot outweigh an individual's First Amendment right to avoid becoming the courier for such message." *Wooley*, 430 U.S. at 717. If the government thinks market prices charged by

prescription drug manufacturers are "unfair," it is free to speak its mind. But it is not free to force manufacturers to declare that below-market prices set by the government are the product of a "negotiation" and are "fair."

255. Nor are the IRA's speech requirements tailored—let alone narrowly tailored—to any interest the government may have in regulating prices. It is "particularly" clear that a law burdening speech is not "properly tailored" when much less burdensome alternatives "are obvious." *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1238 (10th Cir. 1999). Here, Congress could have regulated prices "without burdening a speaker with unwanted speech." *NIFLA*, 138 S. Ct. at 2376 (quoting *Riley v. Nat'l Fed'n of Blind of N.C., Inc.*, 487 U.S. 781, 800 (1988)). Price controls do not require speech controls. But instead, seeking political cover, Congress chose to "co-opt the [pharmaceutical companies] to deliver its message for it." *Id.* Under the First Amendment, "such compulsion . . . plainly violates the Constitution." *Janus*, 138 S. Ct. at 2464.

256. Moreover, even if manufacturers were genuinely free to withdraw from Medicare and Medicaid (they are not, as explained above) and thereby avoid the unwanted speech, that would not solve the IRA's First Amendment problem.

257. Under the "unconstitutional conditions doctrine," it is "'well-settled'" that "'the government may not deny a benefit to a person because he exercises a constitutional right.'" *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994) & *Regan v. Taxation With Representation*, 461 U.S. 540, 545 (1983)) (collecting cases). The Supreme Court has "made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972). What the government cannot "command

directly," it cannot accomplish indirectly by "deny[ing] a benefit to a person on a basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech." *Id*.

258. Here, this principle means that the government cannot condition participation in Medicare on the surrender of manufacturers' right to refrain from espousing the government's views. The requirement that manufacturers endorse government-set prices as the "fair" product of a joint "agreement" is not "'an appropriate requirement for the effective performance' of the [program] in question." *O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 725 (1996) (quoting *Branti v. Finkel*, 445 U.S. 507, 518 (1980)). As discussed above, that mandate is pure political cover—a gratuitous burden on the freedom of speech that does not serve any legitimate government interest.

259. The IRA's compelled-speech provisions are therefore unconstitutional under the First Amendment and must be enjoined.

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court:

260. Declare that the IRA's drug price control program violates the separation of powers, including the nondelegation doctrine;

261. Declare that the IRA's drug price control program violates the Due Process Clause of the Fifth Amendment;

262. Declare that the IRA's "excise tax" violates the Excessive Fines Clause;

263. Declare that the IRA's "excise tax" exceeds Congress's enumerated powers;

264. Declare that the IRA's drug price control program violates the First Amendment;

265. Enjoin HHS from applying the IRA's compelled-speech provisions;

266. Enjoin HHS from implementing the IRA's drug price control program;

267. Enjoin HHS from enforcing the IRA's "excise tax";

268. Award Plaintiffs reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

269. Grant such other and further relief as the Court may deem appropriate.

Dated: October 13, 2023

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